

Preliminary Remarks:

In an effort to facilitate prosecution and to place the present application in better form for allowance (or to narrow the issues for Appeal), applicants have amended claims 1-3, 5, and 13 to specifically recite embodiments of their inventive composition which comprise Poloxamer 188. Applicants' claim amendments are consistent with their response to the Restriction Requirement of February 27, 2006 choosing compositions comprising Poloxamer 188. Additional amendments to claim 3 were made to eliminate redundancies. Accordingly, applicants respectfully submit that entry of these claim amendments after final rejection is proper. Upon reconsideration, if any additional grounds for rejection are deemed necessary, withdrawal of the finality of the prior rejection is respectfully requested.

Remarks:

Claims 1-6, 8-14, and 17-24 are pending. Claims 7 and 15-16 have been cancelled. Pursuant to applicants' response to the Restriction Requirement of February 27, 2006, applicants hereby withdraw claims 17-24 from prosecution without prejudice to prosecution of those claims at a later date.

The Office Action of June 29, 2006 (hereinafter "the Office Action") rejected all pending claims. Claims 1-6, 8-14, and 17-18 were rejected for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1 based on "possession of the invention." Claims 1-6 and 17-24 were rejected for failing to comply with the written description requirement of § 112, ¶ 1 based on "new subject matter." Finally, claims 1-6, 8-14, and 17-24 were provisionally rejected under the doctrine of obviousness-type double patenting in light of the claims of co-pending U.S. Application 10/677,747.

35 U.S.C. § 112, ¶ 1: Claims 1-6, 8-14, and 17-18

The Office Action rejected claims 1-6, 8-14, and 17-18, stating that applicants' claims "contain[] subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the invention was filed, had possession of the claimed invention."

Applicants respectfully submit that this rejection has been mooted by the claim amendments submitted herewith. Claims 17-18 are withdrawn. Applicants' amendments to independent claim 1, as well as claims 2, 3, 5 and 13 depending therefrom, are directed to compositions comprising Poloxamer 188. These amendments are consistent with applicants'

election of "Poloxamer 188 and claims directed to compositions including Poloxamer 188 as the species for which examination is requested" in response to the restriction requirement of February 27, 2006.

35 U.S.C. § 112, ¶ 1: Claims 1-6 and 17-24

The Office Action rejected claims 1-6 and 17-24, stating that "[t]he claim(s) contain new subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

Applicants respectfully traverse this rejection. Claim 1, as presented in applicants' Amendment of December 23, 2005, read:

1. (Currently amended) [[An]] A sterile aqueous pharmaceutical composition for parenteral administration of propofol, said composition comprising propofol and one or more excipient, wherein said composition is stored in a container having a means for dispensing the composition, and wherein the total propofol degradants of the solution when maintained at 25 °C, 40 °C, or 60 °C for 4 weeks are present in an amount of less than 5% (w/v) of said composition.

At the time of that amendment, applicants' remarks also indicated that "[s]upport for the amendments in claim 1 can be found, *inter alia*, in original claim 7 and page 2, line 26, at page 6, lines 15-22, and at page 32, lines 16-23."

As a first basis for the presently pending rejection, the final Office Action stated that "[o]riginal claim 7 cites stability conditions where claim 1 now lacks that limitation." However, the final limitation of claim 1 clearly recited the stability limitation "wherein the total propofol degradants of the solution when maintained at 25 °C, 40 °C, or 60 °C for 4 weeks are present in an amount of less than 5% (w/v) of said composition." The 4-week period and identified temperatures correspond explicitly to one of the three alternate limitations (here, "a") identified in original claim 7 which read as follows:

7. The composition of Claim 1 wherein:

- a) said composition is is stable for 4 weeks at 25, 40, or 60 degrees Celcius;
- b) said composition is stable for 8 weeks at 25, 40, or 60 degrees Celcius; or

c) said composition is stable for 12 weeks at 25, 40, or 60 degrees Celcius.

As a second basis for this rejection, the Office Action stated that "[a]t page 2 line 2 cites accidental extrinsic contamination and the trademarked name Diprivan which are not mentioned in the amended claim 1." However, applicants' did not direct the Examiner's attention to **line 2** of page 2. Applicants' directed the Examiner's attention to **line 26** of page wherein the specification states that "[t]he propofol containing compositions are preferably sterile and parenterally administered to any animal, including humans." This statement from the specification supplied support for the preamble of claim 1.

As a third basis for this rejection, the Office Action stated that "page 6 lines 15-22, cites specific percent propofol degradants, none of which are in the amended claim 1 as well as a refrigerated 6 month storage disclosure which also is not in amended claim 1."

The text of page 6, lines 15-22 of applicants' disclosure contains the support applicants required. The text reads:

wherein the **total propofol degradants** of the solution maintained at one of the following: a) 4 °C, b) 8 °C, **c) 25 °C, d) 40 °C, or e) 60 °C**; at either 65% or 75% relative humidity; for one of the following: **4 weeks**, 8 weeks, 13 weeks, 26 weeks, or 1 year; wherein the total propofol degradants is one of the following: **less than 5%**, 4%, 3%, 2%, 1.5%, 1%, 0.5%, 0.25%, 0.1%, 0.05%, 0.01% total propofol degradants, or not detectable. (emphases added)

The above-quoted portion of applicants' specification does disclose refrigerated temperatures (4 °C and 8 °C) but these lower temperatures (like the elevated temperatures, humidity, time period, and total propofol degradant percentage levels) are identified in the alternative. Applicants were not obligated to recited every limitation identified.

Accordingly, for the reasons stated above, applicants respectfully submit that the final Office Action's "new matter" rejection of claim 1 was improper and should be withdrawn.

Likewise, because the Office Action did not indicate separate, distinct deficiencies in the support for claims 2-6 or 17-24, applicants' interpret the remaining rejections to be premised on the same erroneous grounds cited for the rejection of claim 1. Therefore applicants respectfully submit that the rejection of these claims should also be withdrawn.

Moreover, the applicants' claims, as currently amended, recite compositions that likewise are not new subject matter. The amended claims find support for their specific recitation of Poloxamer 188 throughout applicants' disclosure, including, but not limited to, the following portions of the specification as originally filed: page 16, line 21 to page 17, line 25; page 20, line 4 to page 23, line 6; and page 27, lines 1 to 28.

Provisional Obviousness-type Double Patenting: Claims 1-6, 8-14, and 17-24

The Office Action also provisionally rejected claims 1-6, 8-14, and 17-24 in light of the claims of co-pending U.S. Application 10/677,747.

Applicants will address this rejection by filing a terminal disclaimer, if needed, when the claims have been deemed otherwise allowable and this rejection has been made final.

Conclusion

Applicants believe their response to be fully responsive to the Office Action. For the reasons stated above, applicants believe the application as amended is in condition for allowance. A notice to this effect is respectfully requested.

Respectfully submitted,



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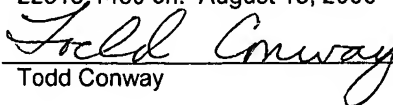
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